AMENDED CLAIMS

1 to 122. *CANCELLED*

123. *(Currently amended)* A concentrated hormone composition for use in compounding a pharmaceutical product for topically delivering one or more steroid hormones to a subject in need of hormone replacement therapy, ~~comprising:~~

~~a) one or more naturally occurring steroid hormone(s); and~~

~~b) a combination of penetration enhancing solvents that promotes delivery of the steroid hormone(s) through the dermis following topical administration;~~

~~with the proviso that the composition is essentially free of water; and~~

~~wherein the combination of penetration enhancing solvents comprises~~

comprising one or more naturally occurring steroid hormone(s) dissolved in a solvent mixture consisting of ethoxy diglycol and propylene glycol.

124. *CANCELLED*

125. *(Currently amended)* ~~The concentrated composition of claim 123, wherein the solvents in the composition consist essentially of about 50%~~

A concentrated hormone composition for use in compounding a pharmaceutical product for topically delivering one or more steroid hormones to a subject in need of hormone replacement therapy, comprising one or more naturally occurring steroid hormone(s) dissolved in a solvent mixture comprising equal volumes of ethoxy diglycol and ~~about 50%~~ propylene glycol.

126. *(Previously presented)* The concentrated composition of claim 123, comprising one or more estrogen(s) at a total concentration of at least 40 mg per gram.

127. *(Previously presented)* The concentrated composition of claim 126, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

128. *(Previously presented)* The concentrated composition of claim 123, comprising at least one androgen at a concentration of at least 150 mg per gram.

129. *(Previously presented)* The concentrated composition of claim 128, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

130. *(Previously presented)* The concentrated composition of claim 123, comprising at least one progestagen at a concentration of at least 200 mg per gram.

131. *(Previously presented)* The concentrated composition of claim 130, wherein said progestagen is selected from progesterone and pregnenolone.

132. *(Currently amended)* A concentrated composition for use in compounding a pharmaceutical product for delivering hormones to a subject in need of hormone replacement therapy, comprising a plurality of different naturally occurring estrogens dissolved ~~or suspended in one or more solvent(s) or wetting agent~~ at a total concentration of least 6 mg of estrogens per gram <u>in a solvent mixture comprising equal volumes of ethoxy diglycol and propylene glycol</u>.

133. *(Previously presented)* The concentrated composition of claim 132, wherein the total concentration of estrogens is between about 10 and 60 mg per gram.

134. *(Previously presented)* The concentrated composition of claim 132, wherein the composition comprises about 40 mg of estrogens per gram.

135. *(Currently amended)* ~~The concentrated composition of claim 132,~~

A concentrated composition for use in compounding a pharmaceutical product for delivering hormones to a subject in need of hormone replacement therapy, comprising a plurality of different naturally occurring estrogens dissolved at a total concentration of least 6 mg of estrogens per gram,

wherein the estrogens ~~are estriol and estradiol, and optionally~~ comprise estriol, estradiol, and estrone.

136. *CANCELLED*

137. *(Previously presented)* The concentrated composition of claim 135, wherein the ratio of estriol, estradiol, and estrone by weight is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

138. *CANCELLED*

139. *(Withdrawn) (Currently amended)* A method for preparing the concentrated composition of any of claims ~~123-138~~ 123-134, comprising:

a) combining said steroid hormone(s) with said ~~solvent(s) or wetting agent~~ solvents; and

b) processing said combination in an ointment mill or homogenizer ~~to decrease particle size~~ to achieve complete dissolution of said hormone(s) in the solvents.

140. *(Currently amended)* A plurality of concentrated hormone compositions according to any of claims ~~123-138~~ 123-137.

141. *(Currently amended)* A reagent system for compounding pharmaceutical products for use in hormone replacement therapy,

wherein the system allows the product to be custom tailored for each individual consumer;

wherein the system comprises a plurality of concentrated hormone reagent compositions, each of which ~~contains:~~

~~a) one or more steroid hormone(s); and~~

~~b) one or more penetration enhancing solvent(s) or wetting agents wherein said compositions are sufficiently concentrated so that they may be compounded into a pharmaceutical product each in an amount that is custom tailored to the needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product~~ contains one or more steroid hormone(s) dissolved in one or more solvent(s);

wherein at least one concentrated hormone reagent composition in the system contains hormone(s) that are different from what is in another concentrated hormone reagent composition in the system; and

wherein each of said compositions comprises a sufficient concentration of said one or more hormone(s) such that when combined with other compositions in the system to form a custom tailored pharmaceutical product, the amount of said hormone(s) in the product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

142. *(Previously presented)* The pharmaceutical compounding system of claim 141, wherein each concentrated reagent composition is contained in a graduated dispensing device.

143. *(Currently amended)* The pharmaceutical compounding system of claim 141, wherein the ~~penetration enhancing~~ solvents are ethoxy diglycol and propylene glycol.

144. *(Currently amended)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing one or more estrogen(s) dissolved at a total concentration of at least 40 mg per gram.

145. *(Previously presented)* The pharmaceutical compounding system of claim 144, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

146. *(Currently amended)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing a plurality of different estrogens dissolved at a total concentration of between 10 and 60 mg of estrogens ~~per gram~~ per gram.

147. *(Currently amended)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing at least one androgen dissolved at a concentration of at least 150 mg per gram.

148. *(Previously presented)* The pharmaceutical compounding system of claim 147, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

149. *(Currently amended)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition at least one progestagen dissolved at a concentration of at least 200 mg per gram.

150. *(Previously presented)* The pharmaceutical compounding system of claim 149, wherein said progestagen is selected from progesterone and pregnenolone.

151. *(Previously presented)* The pharmaceutical compounding system of claim 141, comprising a plurality of concentrated reagent compositions, each containing a different estrogen.

152. *(Previously presented)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition comprising estriol and a concentrated reagent composition comprising estradiol.

153. *(Previously presented)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition comprising estriol, a concentrated reagent comprising estradiol, and a concentrated reagent comprising estrone.

154. *(Previously presented)* The pharmaceutical compounding system of claim 141, wherein the concentrated reagent compositions can be compounded into a pharmaceutical product comprising a therapeutically effective amount of estriol, estradiol, and estrone at a ratio of 8:1:1, 5:4:1, 6:3:1, or 7:2:1 by weight.

155. *(Previously presented)* The pharmaceutical compounding system of any of claims 141-154, further comprising a separate pharmaceutical carrier for combining with the concentrated reagent compositions to produce a pharmaceutical product formulated as an ointment, cream, gel, or paste.

156. *(Previously presented)* The pharmaceutical compounding system of any of claims 141-154, wherein each of said concentrated reagent compositions comprises a colorant.

157. *(Previously presented)* The pharmaceutical compounding system of claim 156, wherein combination of some of said reagents into a particular pharmaceutical product produces a distinct color profile that can be used to confirm the identity of the hormone(s) in that product.

158. *(Previously presented)* A kit comprising the concentrated reagent compositions of the pharmaceutical compounding system of any of claims 141-154.

159. *(Withdrawn) (Currently amended)* A method for preparing the pharmaceutical compounding system of any of claims 141-154, comprising for each of said reagent compositions:

a) combining steroid hormone(s) with ~~penetration enhancing~~ said solvent(s); and

b) processing said combination in an ointment mill or homogenizer ~~to decrease particle size~~ to achieve complete dissolution of said hormone(s) in the solvent(s).

160. *(Currently amended)* A method for compounding a pharmaceutical product for administering one or more hormones to a consumer in need of hormone replacement therapy,

whereby the product is custom tailored for each individual consumer,

the method comprising:

~~a) obtaining one or more concentrated reagent compositions, each comprising one or more steroid hormone(s) in one or more penetration enhancing solvent(s) or wetting agents~~;

a) obtaining a plurality of concentrated reagent compositions, each comprising one or more steroid hormone(s) dissolved in one or more solvent(s);

b) ascertaining the needs of an individual consumer;

c) compounding one or more of said concentrated reagent composition(s) into said pharmaceutical product at a ratio that is custom tailored to the individual needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

161. *(Previously presented)* The compounding method of claim 160, wherein the needs of each consumer are ascertained by way of a prescription from a doctor for replacement of particular hormone(s) each in a particular amount.

162. *(Currently amended)* The compounding method of claim 160, comprising combining a plurality of said concentrated reagent compositions such that the final concentration of the hormone(s) from each concentrated reagent composition in the pharmaceutical product is therapeutically effective for the consumer.

163. *(Previously presented)* The compounding method of claim 160, wherein the concentrated reagent composition(s) are compounded with a suitable pharmaceutical carrier to produce a pharmaceutical product formulated as an ointment, cream, gel or paste.

164. *(Previously presented)* The compounding method of claim 160, wherein the penetration enhancing solvents are ethoxy diglycol and propylene glycol.

165. *(Currently amended)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains one or more estrogen(s) dissolved at a total concentration of at least 40 mg per gram.

166. (Previously presented) The compounding method of claim 165, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

167. (Currently amended) The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains a plurality of estrogen(s) dissolved at a total concentration of between 10 and 60 mg of estrogens per gram.

168. *(Currently amended)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one androgen dissolved at a concentration of at least 150 mg per gram.

169. *(Previously presented)* The compounding method of claim 168, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

170. *(Currently amended)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one progestagen dissolved at a concentration of at least 200 mg per gram.

171. *(Previously presented)* The compounding method of claim 170, wherein said progestagen is selected from progesterone and pregnenolone.

172. *(Previously presented)* The compounding method of claim 160, comprising combining a plurality of concentrated reagent compositions, each containing a different estrogen.

173. *(Previously presented)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol and estradiol.

174. *(Previously presented)* The compounding method of claim 173, wherein the ratio of estriol:estradiol by weight in the final product is 5:5, 6:4, 7:3, 8:2, or 9:1.

175. *(Previously presented)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol, estradiol, and estrone.

176. *(Previously presented)* The compounding method of claim 175, wherein the ratio of estriol, estradiol, and estrone by weight in the final product is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

177. *(Previously presented)* The compounding method of any of claims 160-176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying the identity of the hormone(s) in the product according to the color of the pharmaceutical product after compounding.

178. *(Previously presented)* The compounding method of any of claims 160-176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying that the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

179. *(Previously presented)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a patient for replacement or supplementation of one or more hormone(s); and

b) prescribing for the patient a pharmaceutical product that is compounded according to the method of any of claims 160-176, whereby the product is customized to the individual needs of the subject determined in step a).

180. *(Previously presented)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a consumer for replacement or supplementation of one or more hormone(s);

b) compounding a pharmaceutical product according to the method of any of claims 160-176, whereby the product is customized to the individual needs of the subject determined in step a); and

c) providing said pharmaceutical product to the consumer.

181. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded using the pharmaceutical production system of claim 156, comprising:

a) observing the color of the pharmaceutical product after compounding;

b) deducing the identity of the hormone(s) in the product from the color; and

c) comparing the hormone(s) in the product with the hormone(s) that need supplementation in a particular consumer.

182. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 177, comprising:

a) observing the color of the pharmaceutical product after compounding;

b) deducing the identity of the hormone(s) in the product from the color; and

c) comparing the hormone(s) in the product with the hormone(s) that need supplementation in a particular consumer.

183. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded using the pharmaceutical production system of claim 156, comprising determining whether the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

184. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 178, comprising determining whether the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.